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FILED
AUG 14 2015
MICHAEL E. KUNZ, Clerk
By Dep. Clerk

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

Virginia Gast,

Plaintiff,

v.

BAYER HEALTHCARE PHARMACEUTICALS, INC.; BAYER CORPORATION; JOHNSON & JOHNSON; JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C.; JANSSEN RESEARCH & DEVELOPMENT, LLC; JANSSEN PHARMACEUTICALS, INC. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC; MERCK & CO., INC. and DOES 1-100.

Defendants.

Case No.:

COMPLAINT FOR DAMAGES
AND
DEMAND FOR JURY TRIAL

15 4630

COMES NOW the Plaintiff Virginia Gast, by and through the undersigned counsel, hereby brings this Complaint for damages against the Defendants, and alleges the following:

INTRODUCTION

1. This is an action for damages suffered by Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, advertising, distribution, labeling, and/or sale of the pharmaceutical drug Cipro® (also known as ciprofloxacin), Levaquin® (also known as levofloxacin) and/or Avelox® (also known as moxifloxacin). Cipro® in any of its forms shall herein be referred to as "Cipro." Levaquin® in any of its forms shall herein be referred to as "Levaquin." Avelox® in any of its forms shall herein be referred to as "Avelox."

2. Plaintiff maintains that the drugs Cipro and/or Levaquin and/or Avelox are defective, dangerous to human health, unfit and unsuitable to be marketed and sold in

commerce, and lacked proper warnings and directions as to the dangers associated with its use.

3. Plaintiff's injuries, like those striking thousands of similarly situated victims across the country were avoidable.

PARTIES

4. Plaintiff Virginia Gast is a natural person and at all relevant times a resident and citizen of the Russellville, Ohio. Plaintiff brings this action for personal injuries sustained by the use of Cipro and/or Levaquin and/or Avelox. As a direct and proximate result of being prescribed and ingesting Cipro and/or Levaquin and/or Avelox, Plaintiff developed peripheral neuropathy and/or symptoms of peripheral neuropathy.

5. Defendant Bayer Healthcare Pharmaceuticals, Inc. ("Bayer Healthcare") is a Delaware corporation that has its principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045.

6. In January 2008, Bayer Pharmaceuticals Corporation was merged into Bayer HealthCare Pharmaceuticals Inc.

7. Defendant Bayer Healthcare has transacted and conducted business within the State of Pennsylvania.

8. Defendant Bayer Healthcare has derived substantial revenue from goods and products used in the State of Pennsylvania.

9. Defendant Bayer Healthcare expected or should have expected its acts to have consequences within the State of Pennsylvania, and derived substantial revenue from interstate commerce.

10. Defendant Bayer Healthcare was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Cipro.

11. Defendant Bayer Corporation ("Bayer Corp.") is an Indiana corporation that has its principal place of business at 100 Bayer Road, Pittsburgh, Pennsylvania 15205.

12. Defendant Bayer Corp. has transacted and conducted business within the States

of Pennsylvania and Ohio.

13. Defendant Bayer Corp. has derived substantial revenue from goods and products used in the State of Pennsylvania and Ohio.

14. Defendant Bayer Corp. expected or should have expected its acts to have consequences within the State of Pennsylvania and derived substantial revenue from interstate commerce.

15. Defendant Bayer Corp. was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Cipro.

16. Defendant Johnson & Johnson is a New Jersey corporation that has its principal place of business at One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933.

17. Defendant Johnson & Johnson has transacted and conducted business within the State of Pennsylvania.

18. Defendant Johnson & Johnson has derived substantial revenue from goods and products used in the State of Pennsylvania.

19. Defendant Johnson & Johnson expected or should have expected its acts to have consequences within the State of Pennsylvania, and derived substantial revenue from interstate commerce.

20. Defendant Johnson & Johnson was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Levaquin.

21. Defendant Johnson & Johnson Pharmaceutical Research & Development, L.L.C. ("Johnson & Johnson PRD") is a limited liability company organized under the laws of New Jersey, which has its principal place of business at 920 Route 202 South, P.O. Box 300, Mail Stop 2628, Raritan, New Jersey 08869.

22. Defendant Johnson & Johnson PRD has transacted and conducted business

within the State of Pennsylvania.

23. Defendant Johnson & Johnson PRD has derived substantial revenue from goods and products used in the State of Pennsylvania.

24. Defendant Johnson & Johnson PRD expected or should have expected their acts to have consequences within the State of Pennsylvania, and derived substantial revenue from interstate commerce.

25. At all times material hereto, Defendant Johnson & Johnson PRD was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Levaquin.

26. Defendant Johnson & Johnson PRD is part of the Defendant Johnson & Johnson's "Family of Companies."

27. Defendant Janssen Research & Development, LLC is a limited liability company organized under the laws of New Jersey, which has its principal place of business at 920 Route 202 South, P.O. Box 300, Mail Stop 2628, Raritan, New Jersey 08869.

28. Defendant Janssen Research & Development, LLC has transacted and conducted business within Pennsylvania at 200 Great Valley Parkway, Malvern, Pennsylvania.

29. Defendant Janssen Research & Development, LLC has derived substantial revenue from goods and products used in Pennsylvania and Ohio.

30. Defendant Janssen Research & Development, LLC expected or should have expected their acts to have consequences within Pennsylvania, and derived substantial revenue from interstate commerce.

31. At all times material hereto, Defendant Janssen Research & Development, LLC was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Levaquin.

32. Defendant Janssen Research & Development, LLC is part of the Defendant Johnson & Johnson's "Family of Companies."

33. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation which has

its principal place of business at 1000 Route 202 South, P.O. Box 300, Raritan, New Jersey 08869.

34. Defendant Janssen Pharmaceuticals, Inc. has transacted and conducted business within Pennsylvania and Ohio.

35. Defendant Janssen Pharmaceuticals, Inc. has derived substantial revenue from goods and products used in Pennsylvania and Ohio.

36. Defendant Janssen Pharmaceuticals, Inc. expected or should have expected their acts to have consequences within Pennsylvania and Ohio, and derived substantial revenue from interstate commerce.

37. At all times material hereto, Defendant Janssen Pharmaceuticals, Inc. was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Levaquin.

38. Defendant Janssen Pharmaceuticals, Inc. is a wholly owned subsidiary of Defendant Johnson & Johnson.

39. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. (hereinafter "Ortho-McNeil") is a Delaware corporation which has its principal place of business at 1000 Route 202 South, P.O. Box 300, Raritan, New Jersey 08869.

40. Defendant Ortho-McNeil has transacted and conducted business within the State of Pennsylvania.

41. Defendant Ortho-McNeil has derived substantial revenue from goods and products used in the State of Pennsylvania and Ohio.

42. Defendant Ortho-McNeil expected or should have expected their acts to have consequences within the State of Pennsylvania, and derived substantial revenue from interstate commerce.

43. At all times material hereto, Defendant Ortho-McNeil was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Levaquin.

44. Defendant Ortho-McNeil is a wholly owned subsidiary of Defendant Johnson & Johnson.

45. Defendant Merck & Co., Inc. ("Merck") is a New Jersey corporation that has its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

46. Defendant Merck has transacted and conducted business within the States of Pennsylvania and Ohio.

47. Defendant Merck has transacted and conducted business within the State of Pennsylvania at its facility in West Point, Pennsylvania.

48. Defendant Merck has derived substantial revenue from goods and products used in the State of Pennsylvania.

49. 23. Defendant Merck expected, or should have expected, their acts to have consequences within the State of Pennsylvania, and derived substantial revenue from interstate commerce.

50. 24. At all times material hereto, Defendant Merck was engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Avelox.

51. As used herein, "Defendants" includes all named Defendants.

52. Defendants are authorized to do business in Pennsylvania and derive substantial income from doing business in this state.

53. Upon information and belief, Defendants purposefully availed themselves of the privilege of conducting activities with Pennsylvania, thus invoking the benefits and protections of its laws.

54. Upon information and belief, Defendants did act together to design, sell, advertise, manufacture and/or distribute Cipro and/or Levaquin and/or Avelox, with full knowledge of its dangerous and defective nature.

JURISDICTION AND VENUE

55. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332 because

the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because Defendants are all incorporated and have their principal place of business outside of the state in which the Plaintiff resides.

56. The Court also has supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

57. Venue is proper in this county pursuant to 28 U.S.C. § 1391, in that the Defendants conduct business here and are subject to personal jurisdiction in this District. Furthermore, Defendants sell, market, and/or distribute Cipro and/or Levaquin and/or Avelox within Ohio and this District.

FACTUAL ALLEGATIONS

58. At all relevant times, Defendants Bayer Healthcare, Bayer Corp. was in the business of and did design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or have acquired and are responsible for Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed the pharmaceutical drug Cipro.

59. Cipro was approved by the United States Food and Drug Administration (hereinafter "FDA") in October 1987 for use in the United States, and is the brand name for the antibiotic ciprofloxacin.

60. Cipro is a broad-spectrum antibiotic used to treat certain infections caused by certain germs called bacteria.

61. Cipro is a member of the quinolone class of antibiotics. Quinolones are divided into four generations based on their spectrum of antimicrobial activity.

62. The first generation, non-fluorinated quinolone antibiotics were developed in the early 1960s and soon revealed themselves as effective against common gram-negative bacteria, but resistance developed rapidly.

63. Twenty years later, in the early 1980s, fluorinated derivates of the quinolones emerged, revealing a broader, more potent antibiotic, effective against common gram-negative and gram-positive bacteria. These so-called second generation quinolones included Noroxin®

(norfloxacin), Cipro® (ciprofloxacin), Floxin® (ofloxacin), and pefloxacin (never approved for marketing in the United States).

64. Fluoroquinolones have long been associated with serious side effects. Indeed, many fluoroquinolones have been removed from the United States market due to intolerable adverse events. For example, Omniflox® (temafloxacin) was removed from the market in June 1992 only six months after approval due to low blood sugar, kidney failure, and a rare form of anemia; Trovan® (trovafloxacin) was removed from the market in June 1999 due to severe liver toxicity; Raxar® (grepafloxacin) was removed from the market in October 1999 due to QT-interval prolongation; Zagam® (sparfloxacin) was removed from the market in July 2001 due to QT-interval prolongation; and most recently, Tequin® (gatifloxacin) was removed from the market in May 2006 amid reports of severe blood sugar reactions such as hyperglycemia and hypoglycemia.

65. In 1999 Cipro amassed more than $1 billion in sales in the United States, the first Bayer product to ever do so.

66. In 2002, Cipro became the best-selling antibiotic in the world.

67. Defendant Bayer Healthcare has indicated on its website that Cipro is the "gold standard" treatment for many infections, with an "extensive and unprecedented safety profile" that included being "studied and documented in over 37,000 publications."

68. Levaquin was approved by the United States Food and Drug Administration (hereinafter "FDA") on December 20, 1996, for use in the United States, and is the brand name for the antibiotic levofloxacin.

69. Levaquin is a broad-spectrum fluoroquinolone antibiotic used to treat lung, sinus, skin, and urinary tract infections caused by certain germs called bacteria.

70. In 2003, after generic versions of Cipro (a competing fluoroquinolone antibiotic) went on the market, Levaquin became the number one prescribed fluoroquinolone in the United States.

71. In 2006, after generic versions of Zithromax, a highly popular macrolide

antibiotic, went on the market, Levaquin became the number one prescribed antibiotic in the world.

72. In 2007, Levaquin was ranked 37 of the top 200 drugs that were prescribed in the United States.

73. In 2007, Levaquin was ranked 19th in world sales of prescribed drugs.

74. In 2007, Levaquin accounted for 6.5% of Johnson & Johnson's total revenue, generating $1.6 billion in revenue, an 8% increase over the previous year.

75. Defendant Ortho-McNeil indicates on its website that "[i]n a large number of clinical trials, Levaquin has been shown to have a proven safety and efficacy profile for the treatment of many bacterial infections."

76. Avelox is a broad-spectrum synthetic antibacterial agent marketed and sold in oral tablet, IV solution, and ophthalmic solution, used to treat lung, sinus, skin, and urinary tract infections caused by certain germs called bacteria.

77. Avelox was approved by the United States Food and Drug Administration (hereinafter, the "FDA") on December 10, 1999 for use in the United States, and is the brand name for the antibiotic moxifloxacin.

78. With the patent for Cipro® (Defendants' other blockbuster fluoroquinolone) set to expire in 2003, Defendants set out to develop and effectively market Avelox in order to be more competitive with third- and fourth-generation fluoroquinolones, including Levaquin®. Avelox quickly became Defendants' heir apparent and successor to Cipro®.

79. Similar to Cipro®, Avelox® has proven to be a blockbuster drug for Bayer. In 2007 alone, Avelox® generated international sales of $697.3 million dollars.

80. Defendant Bayer Healthcare has indicated on its website that Avelox is "safe and effective" and "has a well-characterized safety profile, which has been studied in over 14,000 patients in clinical trials and 92,000 patients in post marketing surveillance studies."

81. However, the scientific evidence has established a clear association between Cipro and/or Levaquin and/or Avelox and an increased risk of long-term and sometimes

irreversible peripheral neuropathy.

82. Defendants knew or should have known that Cipro and/or Levaquin and/or Avelox is associated with an increased risk of developing irreversible peripheral neuropathy.

83. Defendants failed to appropriately and adequately inform and warn Plaintiff and Plaintiff's prescribing physicians of the serious and dangerous risks associated with the use of Cipro and/or Levaquin and/or Avelox concerning peripheral neuropathy, as well as other severe and personal injuries, which are permanent and/or long-lasting in nature, cause significant physical pain and mental anguish, diminished enjoyment of life, and the need for medical treatment, monitoring and/or medications.

84. The warning label for Cipro and/or Levaquin and/or Avelox during the period from September 2004 through August 2013 misled Plaintiff and Plaintiff's treating physician by incorrectly advising patients and physicians that peripheral neuropathy associated with Cipro and/or Levaquin and/or Avelox was "rare" and in any case could be avoided by discontinuing the drug upon the onset of certain symptoms. The truth, however, is that the onset of irreversible peripheral neuropathy is often rapid and discontinuation of the drug will not ensure that the peripheral neuropathy is reversible.

85. Though this injury can be significant and debilitating, the language regarding the "rare" risk of peripheral neuropathy was buried at the bottom of a long list of adverse reactions that were included on the Cipro and/or Levaquin and/or Avelox label; the language was in no way highlighted for the benefit of prescribing physicians and patients.

86. Additionally, Defendants failed to disseminate a "Dear Doctor" letter to physicians concerning the label change or the risk of irreversible peripheral neuropathy, and Defendants failed to disclose this serious and dangerous effect when promoting Cipro and/or Levaquin and/or Avelox to physicians.

87. Despite their knowledge that Cipro and/or Levaquin and/or Avelox was associated with an elevated risk of permanent nerve damage, Defendants' promotional campaign was focused on Cipro and/or Levaquin and/or Avelox's purported "safety profile."

88. As early as 1992, there was evidence of the association between fluoroquinolone antibiotics and peripheral neuropathy. Dr. Aoun from the Infectious Diseases Clinic and Microbiology Laboratory at the Institut Jules Bordet in Belgium, along with others, wrote a letter to the editor of the Lancet raising concerns about a 37-year old patient who developed peripheral neuropathy after taking fluoroquinolones.

89. Four years later, Karin Hedenmalm and Olav Spigset published "Peripheral sensory disturbances related to treatment with fluoroquinolones" based on a review of 37 separate reports of symptoms of peripheral nerve damage, highlighting concerns about numbness, pain, and muscle weakness.

90. One of the first studies in the United States that included the post market experience concerning Levaquin and neuropathy was "Peripheral Neuropathy Associated with Fluoroquinolones" written by Jay S. Cohen.

91. The Cohen paper was published in December 2001 and revealed that adverse events reported by forty-five patients suggested a possible association between fluoroquinolones and long-term peripheral nervous system damage. The study noted in particular the presence of severe and/or persistent nerve problems. Over one-half of the patients surveyed said their symptoms lasted for more than a year, and eighty percent characterized their symptoms as severe. The Cohen paper recommended further investigation of the association between fluoroquinolones and peripheral neuropathy. The study concluded with the following advisory: "If the occurrence of fluoroquinolone-associated ADEs of this severity and duration is confirmed, physicians need to be informed and warnings might be considered for these drugs' product information."

92. In 2002 and 2003 Defendants were put on notice that numerous reports had been submitted to the FDA's Adverse Event Reporting System that identified fluoroquinolone users who had developed disabling peripheral neuropathy that persisted long after the drug had been discontinued.

93. A scientific review by the FDA of the adverse events in the FDA Adverse Event

database in 2003 concerning Levaquin and other fluoroquinolones revealed numerous reports of long-term peripheral neuropathy.

94. In September 2004, an amended label concerning peripheral nerve damage was approved by the FDA for Cipro and/or Levaquin and/or Avelox. The amended labels included the following statement in the respective Warnings sections:

> Peripheral Neuropathy: Rare cases of sensory or sensorimotor axonal polyneuropathy affecting small and/or large axons resulting in paresthesias, hypoesthesias, dysesthesias and weakness have been reported in patients receiving quinolones, including levofloxacin. Levofloxacin should be discontinued if the patient experiences symptoms of neuropathy including pain, burning, tingling, numbness, and/or weakness or other alterations of sensation including light touch, pain, temperature, position sense, and vibratory sensation in order to prevent the development of an irreversible condition

95. Thus, rather than warning patients and physician that the use of Cipro and/or Levaquin and/or Avelox may result in permanent nerve damage, Defendants instead adopted a warning that misleadingly indicated such damage was rare and in any event could be avoided by simply discontinuing the drug upon the onset of certain symptoms.

96. Defendants' failure to adequately warn physicians resulted in (1) patients receiving Cipro and/or Levaquin and/or Avelox instead of another acceptable and adequate non-fluoroquinolone antibiotic, sufficient to treat the illness for which Plaintiff presented to the provider; (2) and physicians failing to warn and instruct consumers about the risk of peripheral nervous system injuries associated with Cipro and/or Levaquin and/or Avelox.

97. The failure of Defendants to include appropriate warnings in the label as published to the medical community also resulted in an absence of adequate warnings in patient information presented directly to consumers, either as part of samples packages or as part of the prescription they received from retail pharmacies.

98. Despite Defendants' knowledge and failure to adequately warn Plaintiff and

physicians of the above, Defendants continue to market Cipro and/or Levaquin and/or Avelox as a first line therapy for common bronchitis, sinusitis and other non-life threatening bacterial infections, conditions for which many other safer antibiotics are available.

99. In August of 2013, after mounting evidence of the relationship between fluoroquinolones and severe, long-term peripheral neuropathy, the FDA determined that the existing warning regarding peripheral nerve damage was inadequate. On August 15, 2013, an updated warning was issued in which the risk of rapid onset of irreversible peripheral neuropathy was finally included. The updated warning also removed the statement that nerve damage occurred only in rare cases.

100. Notwithstanding this updated 2013 label change, the Levaquin label remains inadequate and confusing regarding the risk of developing irreversible peripheral neuropathy. For instance, the Levaquin label currently states under the "Warnings and Precautions" section of the first page as follows: "Peripheral neuropathy: discontinue immediately if symptoms occur in order to *prevent irreversibility* (5.8)." This statement implies to physicians and patients that, if the patient stops using the drug immediately after symptoms occur, the symptoms are reversible. However, in section 5.8, the label states that "Symptoms [of peripheral neuropathy] may occur soon after initiation of LEVAQUIN® and *may be irreversible*." This later statement conflicts with the earlier statement by implying that no matter whether the patient stops using the drug immediately after experiencing symptoms, the symptoms may be permanent. It is inconsistent to advise physicians and patients in one section of the label that that the symptoms of peripheral neuropathy are reversible if the drug is stopped immediately after symptoms occur, but to advise physicians and patients in another section of the label that symptoms may be irreversible no matter whether they stop taking the medication immediately upon experiencing symptoms.

101. Similarly, the 2013 Cipro label remains inadequate and confusing regarding the risk of developing irreversible peripheral neuropathy. For instance, page twelve of the label states "Ciprofloxacin should be discontinued immediately if the patient experiences symptoms of peripheral neuropathy." This implies to physicians and patients that, if the patient should

discontinue use of the drug immediately, the symptoms may subside or disappear. However, in several other sections of the label it is warned that "symptoms [of peripheral neuropathy] may occur soon after initiation of therapy and may be irreversible," and that "peripheral neuropathy that may be irreversible." Further down, the label lists a number of symptoms of peripheral neuropathy and further states, "[t]he nerve damage may be permanent." This earliest statement at the beginning of the label conflicts with the later statements which imply that no matter whether the patient stops using the drug immediately after experiencing symptoms, the symptoms may be permanent. It is inconsistent to advise physicians and patients in one section of the label to simply stop taking the drug if any symptoms arise, but to advise in other sections that these symptoms may in fact be irreversible.

102. In January of 2014, Ayad Ali published "Peripheral neuropathy and Guillain-Barré syndrome risks associated with exposure to systemic fluoroquinolones: a pharmacovigilance analysis" which reemphasized the link between fluoroquinolones and peripheral neuropathy and called for increased scrutiny of the risk-benefit of fluoroquinolone prescriptions. The Ali paper also detailed the presence of strong safety signals dating back to at least 2005 regarding the potential for Cipro and/or Levaquin, and other fluoroquinolones to cause long-term, disabling peripheral neuropathy.

103. Plaintiff experienced symptoms related to peripheral neuropathy including but not limited to stabbing pains through Plaintiff's limbs and numbness, Plaintiff was diagnosed with irreversible peripheral neuropathy Plaintiff's physicians never informed Plaintiff these injuries could be associated with Plaintiff's ingestion of Cipro and/or Levaquin and/or Avelox.

104. Plaintiff was prescribed Cipro and used it as directed. Plaintiff was also prescribed Levaquin and used it as directed. Lastly, Plaintiff was prescribed Avelox and used it as directed.

105. While Plaintiff continued to experience these symptoms, Plaintiff was never warned or informed, and would not have reasonably known, have known, that Plaintiff's symptoms could be associated with the Cipro and/or Levaquin and/or Avelox.

EQUITABLE TOLLING OF APPLICABLE STATUTE OF LIMITATIONS

106. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

107. The running of any statute of limitations has been tolled by reason of Defendants' fraudulent concealment. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiff's treating physicians the true risks associated with Cipro and/or Levaquin and/or Avelox.

108. As a result of Defendants' actions, Plaintiff and, upon information and belief, Plaintiff's treating physicians were unaware, and could not reasonably know, have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' acts and omissions.

109. Plaintiff experienced symptoms related to peripheral neuropathy including but not limited to stabbing pains through Plaintiff's limbs and numbness, Plaintiff was diagnosed with irreversible peripheral neuropathy Plaintiff's physicians never informed Plaintiff these injuries could be associated with Plaintiff's ingestion of Cipro and/or Levaquin and/or Avelox.

110. Plaintiff was prescribed Cipro and used it as directed. Plaintiff was also prescribed Levaquin and used it as directed. Lastly, Plaintiff was prescribed Avelox and used it as directed.

111. While Plaintiff continued to experience these symptoms, Plaintiff was never warned or informed, and would not have reasonably known, have known, that Plaintiff's symptoms could be associated with the Cipro and/or Levaquin and/or Avelox.

112. Furthermore, Defendants are estopped from relying on any statute of limitations because of their fraudulent concealment of the true character, quality and nature of Cipro and/or Levaquin and/or Avelox. Defendants were under a duty to disclose the true character, quality, and nature of Cipro and/or Levaquin and/or Avelox because this was non-public information over which Defendants had and continues to have exclusive control, and because Defendants

knew that this information was not available to the Plaintiff, medical providers and/or to their facilities. In addition, Defendants are estopped from relying on any statute of limitations because of their intentional concealment of these facts.

113. Plaintiff had no knowledge that Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by Defendants, Plaintiff could not have reasonably discovered the wrongdoing at any time prior. Also, the economics of this fraud should be considered. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing, promoting and/or distributing a profitable drug, notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded and could not have possibly conducted studies to determine the nature, extent and identity of related health risks, and were forced to rely on only the Defendants' representations. Accordingly, Defendants are precluded by the discovery rule and/or the doctrine of fraudulent concealment from relying upon any statute of limitations.

114. For each Count hereinafter alleged and averred, the above and following Paragraphs should be considered re-alleged as if fully rewritten.

FIRST CAUSE OF ACTION

[Strict Liability]

115. Plaintiff incorporates all paragraphs of this Complaint as if set forth herein.

116. Cipro and/or Levaquin and/or Avelox was defective at the time of its manufacture, development, production, testing, inspection, endorsement, prescription, sale and distribution in that warnings, instructions and directions accompanying Cipro and/or Levaquin and/or Avelox failed to warn of the dangerous risks posed by Cipro and/or Levaquin and/or Avelox, including the risk of developing irreversible peripheral neuropathy.

117. At all times alleged herein, Cipro and/or Levaquin and/or Avelox was defective and Defendants knew that Cipro and/or Levaquin and/or Avelox was to be used by consumers without inspection for defects. Moreover, Plaintiff, Plaintiff's prescribing physicians, and

Plaintiff's health care providers neither knew nor had reason to know at the time of Plaintiff's use of Cipro and/or Levaquin and/or Avelox of the aforementioned defects. Ordinary consumers would not have recognized the potential risks for which Defendants failed to include the appropriate warnings.

118. At all times alleged herein, Cipro and/or Levaquin and/or Avelox was prescribed to and used by Plaintiff as intended by Defendants and in a manner reasonably foreseeable to Defendants.

119. The design of Cipro and/or Levaquin and/or Avelox was defective in that the risks associated with using Cipro and/or Levaquin and/or Avelox outweighed any benefits of the design. Any benefits associated with the use of Cipro and/or Levaquin and/or Avelox were either relatively minor or nonexistent and could have been obtained by the use of other, alternative treatments and products that could equally or more effectively reach similar results but without the increased risk of developing irreversible peripheral neuropathy.

120. The defect in design existed when the product left Defendants' possession.

121. At the time Cipro and/or Levaquin and/or Avelox left the control of Defendants, Defendants knew or should have known of the risks associated with ingesting Cipro and/or Levaquin and/or Avelox.

122. As a result of Cipro and/or Levaquin and/or Avelox's defective condition, Plaintiff suffered the injuries and damages alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

SECOND CAUSE OF ACTION

[Negligent Failure to Warn]

123. Plaintiff incorporates all paragraphs of this Complaint as if set forth herein.

124. At the time the Cipro and/or Levaquin and/or Avelox left the control of

Defendants, it was without an adequate warning or instruction of the dangerous risks posed by Cipro and/or Levaquin and/or Avelox, including the risk of developing irreversible peripheral neuropathy.

125. These inadequate warnings created an unreasonably dangerous condition that Defendants knew, or in the exercise of ordinary care, should have known, posed a substantial risk of harm to a reasonably foreseeable claimant, including Plaintiff.

126. Moreover, Plaintiff's prescribing physicians, Plaintiff's health care providers, and any other legally authorized person who prescribed or dispensed the Cipro and/or Levaquin and/or Avelox for the Plaintiff were not provided adequate warnings or instruction regarding Cipro and/or Levaquin and/or Avelox's dangers and risks. The dangerous risks posed by Cipro and/or Levaquin and/or Avelox, including the risk of developing irreversible peripheral neuropathy, were neither open nor obvious, nor a matter a common knowledge.

127. The failure to provide adequate warnings and instructions of the risks posed by Cipro and/or Levaquin and/or Avelox were the proximate cause of Plaintiff's harm.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

THIRD CAUSE OF ACTION

[Negligent Design Defect]

128. Plaintiff incorporates all paragraphs of this Complaint as if set forth herein.

129. At the time of Cipro and/or Levaquin and/or Avelox's manufacture Defendants acted unreasonably in designing or formulating the product(s).

130. At the time Cipro and/or Levaquin and/or Avelox left Defendants' control, Defendants unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design or formulation of the product(s) that could then have been reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially

impairing the usefulness, practicality, or desirability of the product.

131. Moreover, at the time the Cipro and/or Levaquin and/or Avelox left the control of Defendants, the design or formulation of the product(s) was so unreasonable that a reasonable person, such as Plaintiff, aware of the relevant facts and risks, such as the risk of irreversible peripheral neuropathy, would not have consumed a product of this design. Defendants acted unreasonably when weighing the risk associated with Cipro and/or Levaquin and/or Avelox, including the possible side effect of developing long-term and potentially irreversible peripheral neuropathy as a result of its use.

132. Defendants acted unreasonable in knowing the unlikelihood of Cipro and/or Levaquin and/or Avelox users, including Plaintiff, having knowledge, whether based on warnings, general knowledge, or otherwise of the risks of harm of ingesting the product, including the possible side effect of developing long-term and potentially irreversible peripheral neuropathy as a result of its use.

133. Cipro and/or Levaquin were not "unavoidably safe," in that the risks associated with the drugs were not reasonably capable of being made safe.

134. The inadequate design and formulation of Cipro and/or Levaquin and/or Avelox was the proximate cause of Plaintiff's harm for which damages are sought.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

FOURTH CAUSE OF ACTION

[Negligence]

135. Plaintiff incorporates all paragraphs of this Complaint as if set forth herein

136. At all times material hereto, Defendants had a duty to exercise reasonable care to consumers, including Plaintiff herein, in the design, development, manufacture, testing, inspection, packaging, promotion, marketing, distribution, labeling, and/or sale of Cipro and/or

Levaquin and/or Avelox.

137. Defendants breached their duty of reasonable care to Plaintiff in that they negligently promoted, marketed, distributed, and/or labeled the subject product.

138. Plaintiff's injuries and damages alleged herein were and are the direct and proximate result of the carelessness and negligence of Defendants, including, but not limited to, one or more of the following particulars:

a) In the design, development, research, manufacture, testing, packaging, promotion, marketing, sale, and/or distribution of Cipro and/or Levaquin and/or Avelox;

b) In failing to warn or instruct, and/or adequately warn or adequately instruct, users of the subject product, including Plaintiff herein, of Cipro and/or Levaquin and/or Avelox's dangerous and defective characteristics;

c) In the design, development, implementation, administration, supervision, and/or monitoring of clinical trials for the subject product;

d) In promoting the subject product in an overly aggressive, deceitful, and fraudulent manner, despite evidence as to the product's defective and dangerous characteristics due to its propensity to cause irreversible peripheral neuropathy;

e) In representing that the subject product was safe for its intended use when, in fact, the product was unsafe for its intended use;

f) In failing to perform appropriate pre-market testing of the subject product;

g) In failing to perform appropriate post-market surveillance of the subject product;

h) In failing to adequately and properly test Cipro and/or Levaquin and/or Avelox before and after placing it on the market;

i) In failing to conduct sufficient testing on Cipro and/or Levaquin and/or Avelox which, if properly performed, would have shown that Cipro

and/or Levaquin and/or Avelox had the serious side effect of causing irreversible peripheral neuropathy;

j) In failing to adequately warn Plaintiff and Plaintiff's healthcare providers that the use of Cipro and/or Levaquin and/or Avelox carried a risk of developing irreversible peripheral neuropathy;

k) In failing to provide adequate post-marketing warnings or instructions after Defendant knew or should have known of the significant risk of irreversible peripheral neuropathy associated with the use of Cipro and/or Levaquin and/or Avelox; and

l) In failing to adequately and timely inform Plaintiff and the healthcare industry of the risk of serious personal injury, namely, irreversible peripheral neuropathy, from Cipro and/or Levaquin and/or Avelox ingestion as described herein.

139. Defendants knew or should have known that consumers, such as Plaintiff herein, would foreseeably suffer injury as a result of Defendants' failure to exercise reasonable and ordinary care.

140. As a direct and proximate result of Defendants' carelessness and negligence, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

FIFTH CAUSE OF ACTION

[Breach of Express Warranty]

141. Plaintiff incorporates all paragraphs of this Complaint as if set forth herein.

142. Before Plaintiff was first prescribed and during the period in which Plaintiff used Cipro and/or Levaquin and/or Avelox, Defendants created an express warranty when making the affirmation of fact or promise that Cipro and/or Levaquin and/or Avelox was safe.

143. Cipro and/or Levaquin and/or Avelox did not conform to these express representations because Cipro and/or Levaquin and/or Avelox was not safe and had an increased risk of serious side effects, including irreversible peripheral neuropathy, whether taken individually or in conjunction with other therapies.

144. As a direct and proximate result of this wrongful conduct, Plaintiff was injured as described above.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

SIXTH CAUSE OF ACTION

[Breach of Implied Warranty]

145. Plaintiff incorporates all paragraphs of this Complaint as if set forth herein

146. At all times mentioned herein, Defendants manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and/or sold Cipro and/or Levaquin and/or Avelox, and prior to the time that it was prescribed to Plaintiff, Defendants impliedly warranted to Plaintiff that the subject product was of merchantable quality and safe and fit for the use for which it was intended.

147. Plaintiff, individually and through Plaintiff's prescribing physicians, reasonably relied upon the skill, superior knowledge, and judgment of Defendants.

148. Plaintiff was prescribed, purchased, and used the subject product for its intended purpose.

149. Due to Defendants' wrongful conduct as alleged herein, Plaintiff could not have known about the nature of the risks and side effects associated with the subject product until after using it.

150. Contrary to the implied warranty for the subject product, Cipro and/or Levaquin and/or Avelox were not of merchantable quality, and it was neither safe nor fit for its intended uses and purposes, as alleged herein.

151. As a direct and proximate result of Defendants' breach of implied warranty, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff seeks actual and punitive damages from Defendant as alleged herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

SEVENTH CAUSE OF ACTION

[Fraud]

152. Plaintiff incorporates all paragraphs of this Complaint as if set forth herein

153. Defendants misrepresented to Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry the safety and effectiveness of Cipro and/or Levaquin and/or Avelox, and/or fraudulently, intentionally, and/or negligently concealed material information, including adverse information, regarding the safety and effectiveness of Cipro and/or Levaquin and/or Avelox.

154. Defendants made misrepresentations and actively concealed adverse information when Defendants knew, or should have known, that Cipro and/or Levaquin and/or Avelox had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physicians, and the healthcare industry generally. Specifically, Defendants

actively concealed from Plaintiff, Plaintiff's prescribing physicians, the health care industry, and the consuming public that:

(a) Since at least 1996 Defendants and/or its predecessors were in possession of data demonstrating that Cipro and/or Levaquin and/or Avelox increases the risk of irreversible peripheral neuropathy;

(b) There had been insufficient studies by Defendants and/or their predecessors regarding the safety and efficacy of Cipro and/or Levaquin and/or Avelox before and after its product launch;

(c) Cipro and/or Levaquin and/or Avelox was not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy; and

(d) Testing and studies by other entities as reported in the scientific literature has shown that the use of Cipro and/or Levaquin and/or Avelox increases the risk of irreversible peripheral neuropathy.

155. These misrepresentations and/or active concealment alleged were perpetuated directly and/or indirectly by Defendants.

156. Defendants knew or should have known that these representations were false, and they made the representations with the intent or purpose of deceiving Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry.

157. Defendants made these false representations with the intent or purpose that Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry would rely on them, leading to the use of Cipro and/or Levaquin and/or Avelox by Plaintiff as well as the general public.

158. At all times herein mentioned, neither Plaintiff nor Plaintiff's physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, and upon information and belief, Plaintiff's physicians would not have prescribed and Plaintiff would not have utilized the subject product.

159. Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry justifiably relied on and/or were induced by Defendants' misrepresentations and/or active concealment and relied on the absence of information regarding the dangers of Cipro and/or Levaquin and/or Avelox that Defendants did suppress, conceal, or fail to disclose to Plaintiff's detriment. Plaintiff justifiably relied, directly or indirectly, on Defendants' misrepresentations and/or active concealment regarding the true dangers of Cipro and/or Levaquin and/or Avelox. Based on the nature of the physician-patient relationship, Defendants had reason to expect that Plaintiff would indirectly rely on Defendants' misrepresentations and/or active concealment.

160. Defendants had a post-sale duty to warn Plaintiff, Plaintiff's prescribing physicians, and the general public about the potential risks and complications associated with Cipro and/or Levaquin and/or Avelox in a timely manner.

161. As a result of Defendants' actions, Plaintiff and, upon information and belief, Plaintiff's treating physicians were unaware, and could not reasonably know, have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' intentional acts and omissions.

162. Plaintiff experienced symptoms related to peripheral neuropathy including but not limited to stabbing pains through Plaintiff's limbs and numbness. Plaintiff's physicians never informed Plaintiff these injuries could be associated with Plaintiff's ingestion of Cipro and/or Levaquin and/or Avelox.

163. While Plaintiff continued to experience these symptoms, Plaintiff was never warned or informed, and would not have reasonably known or have known, that Plaintiff's symptoms could be associated with the Cipro and/or Levaquin and/or Avelox.

164. Defendants made representations and actively concealed information about the defects and dangers of Cipro and/or Levaquin and/or Avelox with the intent and specific desire that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Cipro and/or Levaquin and/or Avelox as a treatment.

165. As a result of the concealment and/or suppression of the material facts set forth above, Plaintiff ingested Cipro and/or Levaquin and/or Avelox and suffered injuries as set forth herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

EIGHTH CAUSE OF ACTION

[Negligent Misrepresentation]

166. Plaintiff incorporates all paragraphs of this Complaint as if set forth herein

167. Defendants negligently and/or recklessly misrepresented to Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry the safety and effectiveness of Cipro and/or Levaquin and/or Avelox, and/or recklessly and/or negligently concealed material information, including adverse information, regarding the safety, effectiveness, and dangers posed by Cipro and/or Levaquin and/or Avelox.

168. Defendants made reckless or negligent misrepresentations and negligently or recklessly concealed adverse information when Defendants knew, or should have known, that Cipro and/or Levaquin and/or Avelox had defects, dangers, and characteristics that were other than what Defendants had represented to Plaintiff, Plaintiff's physician(s) and the healthcare industry generally. Specifically, Defendants negligently or recklessly concealed from Plaintiff, Plaintiff's prescribing physicians, the health care industry, and the consuming public that:

(a) Since at least 1996 Defendants and/or its predecessors were in possession of data demonstrating that Cipro and/or Levaquin and/or Avelox increases the risk of irreversible peripheral neuropathy;

(b) There had been insufficient studies by Defendants and/or their predecessors regarding the safety and efficacy of Cipro and/or Levaquin and/or Avelox before and after its product launch;

(c) Cipro and/or Levaquin and/or Avelox was not fully and adequately tested by Defendants and/or their predecessor for the risk of developing irreversible peripheral neuropathy; and

(d) Testing and studies by other entities as reported in the scientific literature has shown that the use of Cipro and/or Levaquin and/or Avelox increases the risk of irreversible peripheral neuropathy.

169. These negligent or reckless misrepresentations and/or negligent or reckless failures to disclose were perpetuated directly and/or indirectly by Defendants.

170. Defendants should have known through the exercise of due care that these representations were false, and they made the representations without the exercise of due care leading to the deception of Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry.

171. Defendants made these false representations without the exercise of due care knowing that it was reasonable and foreseeable that Plaintiff, Plaintiff's prescribing physicians, and the healthcare industry would rely on them, leading to the use of Cipro and/or Levaquin and/or Avelox by Plaintiff as well as the general public.

172. At all times herein mentioned, neither Plaintiff nor Plaintiff's physicians were aware of the falsity or incompleteness of the statements being made by Defendants and believed them to be true. Had they been aware of said facts, and upon information and belief, Plaintiff's physicians would not have prescribed and Plaintiff would not have utilized the subject product.

173. Plaintiff justifiably relied on and/or was induced by Defendants' negligent or reckless misrepresentations and/or negligent or reckless failure to disclose the dangers of Cipro and/or Levaquin and/or Avelox and relied on the absence of information regarding the dangers of Cipro and/or Levaquin and/or Avelox which Defendants negligently or recklessly suppressed, concealed, or failed to disclose to Plaintiff's detriment.

174. Defendants had a post-sale duty to warn Plaintiff, Plaintiff's prescribing physicians, and the general public about the potential risks and complications associated with

Cipro and/or Levaquin and/or Avelox in a timely manner.

175. Defendants made the representations and actively concealed information about the defects and dangers of Cipro and/or Levaquin and/or Avelox with the absence of due care such that Plaintiff's prescribing physicians and the consuming public would rely on such information, or the absence of information, in selecting Cipro and/or Levaquin and/or Avelox as a treatment.

176. As a result of the negligent or reckless concealment and/or the negligent or reckless failure to provide materials facts set forth above, Plaintiff ingested Cipro and/or Levaquin and/or Avelox and suffered injuries as set forth herein.

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for compensatory and punitive damages, together with interest, costs herein incurred, attorneys' fees, and all such other and further relief as this Court deems just and proper. Plaintiff also demands that the issues herein contained be tried by a jury.

NINTH CAUSE OF ACTION

[Fraudulent Concealment]

177. Plaintiff incorporates all paragraphs of this Complaint as if set forth herein

178. Defendants committed actual fraud by making material representations that were false, knowing that such material representations were false, and/or with reckless disregard for the truth or falsity of such material representations with the intent that Plaintiff and Plaintiff's prescribing physicians would rely on such material representations.

179. As a result of Defendants' actions, Plaintiff and, upon information and belief, Plaintiff's treating physicians were unaware, and could not reasonably know, have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of Defendants' intentional acts and omissions.

180. Plaintiff experienced symptoms for a number of years related to peripheral neuropathy including but not limited to stabbing pains through Plaintiff's limbs and numbness.

Plaintiff's physicians never informed Plaintiff these injuries could be associated with Plaintiff's ingestion of Cipro and/or Levaquin and/or Avelox.

181. While Plaintiff continued to experience these symptoms, Plaintiff was never warned or informed, and would not have reasonably known, have known, that Plaintiff's symptoms could be associated with the Cipro and/or Levaquin and/or Avelox.

182. Thus, Plaintiff and Plaintiff's prescribing physicians were unaware of the falsity of these representations, they acted in actual and justifiable reliance on such material misrepresentations, and Plaintiff was injured as a direct and proximate result.

183. Additionally, Defendants knowingly omitted material information and remained silent regarding said misrepresentations despite the fact that they had a duty to inform Plaintiff, Plaintiff's prescribing physicians, and the general public of the inaccuracy of said misrepresentations, which omission constitutes a positive misrepresentation of material fact, with the intent that Plaintiff and Plaintiff's prescribing physicians would rely on Defendants' misrepresentations. Plaintiff and Plaintiff's prescribing physicians did, in fact, act in actual and justifiable reliance on Defendants' representations, and Plaintiff was injured as a result.

184. At all times herein mentioned, Defendants had a duty to Plaintiff, Plaintiff's prescribing physicians, and the general public to accurately inform them of risks associated with Cipro and/or Levaquin and/or Avelox because Defendants, as the manufacturer and/or distributor of the subject products, were in a position of superior knowledge and judgment regarding any potential risks associated with Cipro and/or Levaquin and/or Avelox.

185. Defendants committed constructive fraud by breaching one or more legal or equitable duties owed to Plaintiff relating to the Cipro and/or Levaquin and/or Avelox at issue in this lawsuit, said breach or breaches constituting fraud because of their propensity to deceive others or constitute an injury to public interests or public policy.

186. In breaching their duties to Plaintiff, Defendants used their position of trust as the manufacturer and/or distributor of Cipro and/or Levaquin and/or Avelox to increase sales of

Plaintiff of necessary information to enable Plaintiff to weigh the true risks of using Cipro and/or Levaquin and/or Avelox against its benefits.

8. As a direct and proximate result of Defendants' willful, wanton, careless, reckless, conscious, and deliberate disregard for the rights and safety of their consumers, Plaintiff suffered severe and permanent physical and emotional injuries, including, but not limited to, irreversible peripheral neuropathy. Plaintiff has endured pain and suffering, has suffered economic loss, including incurring significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff's injuries and damages are permanent and will continue into the future.

9. Defendants' aforesaid conduct was committed with knowing, conscious, careless, reckless, willful, wanton, and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendants as follows:

(a) For general (non-economic) and special (economic) damages in a sum in excess of the jurisdictional minimum of this Court;

(b) For medical, incidental, and hospital expenses according to proof;

(c) For pre-judgment and post-judgment interest as provided by law;

(d) For full refund of all purchase costs Plaintiff paid for Cipro and/or Levaquin and/or Avelox;

(e) For compensatory damages in excess of the jurisdictional minimum of this Court;

(f) For consequential damages in excess of the jurisdictional minimum of this Court;

(g) For punitive damages in an amount in excess of any jurisdictional minimum of this Court and in an amount sufficient to impress upon

Defendants the seriousness of their conduct and to deter similar conduct in the future;

(h) For attorneys' fees, expenses, and costs of this action; and

(i) For such further relief as this Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues so triable.

Dated: August 10, 2015

Respectfully submitted,

Marc Grossman, Esq.
SANDERS PHILLIPS GROSSMAN LLC
100 Garden City Plaza, Suite 500
Garden City, N.Y. 11501
Telephone: (516) 741-5600
Facsimile: (516) 741-0128
mgrossman@thesandersfirm.com

Attorneys for Plaintiff

15-CV-4630

JS 44 (Rev. 12/12) TON

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

I. (a) PLAINTIFFS
VIRGINIA GAST

(b) County of Residence of First Listed Plaintiff Brown
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Sanders Phillips Grossman, LLC, 100 Garden City Plaza, Suite 500, Garden City, NY 11530

DEFENDANTS
BAYER HEALTHCARE PHARMACEUTICALS, INC. et al.

County of Residence of First Listed Defendant Bergen
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☒ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 USC 1332
Brief description of cause:
Product Liability Pharmaceutical Litigation

VII. REQUESTED IN COMPLAINT:
☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.
DEMAND $ 10,000,000.00
CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*: JUDGE _____ DOCKET NUMBER _____

AUG 14 2015

DATE 08/10/2015

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

TON

UNITED STATES DISTRICT COURT 15 4630

FOR THE EASTERN DISTRICT OF PENNSYLVANIA — DESIGNATION FORM to be used by counsel to indicate the category of the case for the purpose of assignment to appropriate calendar.

Address of Plaintiff: 240 North Middle St., Russellville, OH 45168

Address of Defendant: 340 Changebridge Road, Montville, New Jersey 07045; 100 Bayer Road, Pittsburgh, Pennsylvania 15205, One Johnson & Johnson Plaza, New Brunswick, Middlesex County, New Jersey 08933 et al

Place of Accident, Incident or Transaction: Ohio

(*Use Reverse Side For Additional Space*)

Does this civil action involve a nongovernmental corporate party with any parent corporation and any publicly held corporation owning 10% or more of its stock?

(Attach two copies of the Disclosure Statement Form in accordance with Fed.R.Civ.P. 7.1(a)) Yes☐ No☑

Does this case involve multidistrict litigation possibilities? Yes☑ No☐

RELATED CASE, IF ANY:

Case Number: MDL 2642 Judge Unknown Date Terminated:

Civil cases are deemed related when yes is answered to any of the following questions:

1. Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? Yes☐ No☑
2. Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? Yes☐ No☑
3. Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action in this court? Yes☐ No☑
4. Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? Yes☐ No☑

CIVIL: (Place ✔ in ONE CATEGORY ONLY)

A. *Federal Question Cases*:

1. ☐ Indemnity Contract, Marine Contract, and All Other Contracts
2. ☐ FELA
3. ☐ Jones Act-Personal Injury
4. ☐ Antitrust
5. ☐ Patent
6. ☐ Labor-Management Relations
7. ☐ Civil Rights
8. ☐ Habeas Corpus
9. ☐ Securities Act(s) Cases
10. ☐ Social Security Review Cases
11. ☐ All other Federal Question Cases

(Please specify) _____

B. *Diversity Jurisdiction Cases*:

1. ☐ Insurance Contract and Other Contracts
2. ☐ Airplane Personal Injury
3. ☐ Assault, Defamation
4. ☐ Marine Personal Injury
5. ☐ Motor Vehicle Personal Injury
6. ☐ Other Personal Injury (Please specify)
7. ☑ Products Liability
8. ☐ Products Liability — Asbestos
9. ☐ All other Diversity Cases

(Please specify) _____

ARBITRATION CERTIFICATION

(*Check Appropriate Category*)

I, Marc Grossman, counsel of record do hereby certify:

☒ Pursuant to Local Civil Rule 53.2, Section 3(c)(2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of $150,000.00 exclusive of interest and costs;

☐ Relief other than monetary damages is sought.

DATE: 8/10/2015 Marc Grossman 304859

Attorney-at-Law Attorney I.D.#

NOTE: A trial de novo will be a trial by jury only if there has been compliance with F.R.C.P. 38.

I certify that, to my knowledge, the within case is not related to any case now pending or within one year previously terminated action in this court except as noted above.

DATE: 08/10/2015 _____ 304859

Attorney-at-Law Attorney I.D.#

AUG 14 2015

CIV. 609 (5/2012)

TON

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

Virginia Gast	:	CIVIL ACTION
v.	:	15 4630
Bayer Healthcare, et. al.	:	NO.

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

(a) Habeas Corpus – Cases brought under 28 U.S.C. § 2241 through § 2255. ( )

(b) Social Security – Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ( )

(c) Arbitration – Cases required to be designated for arbitration under Local Civil Rule 53.2. ( )

(d) Asbestos – Cases involving claims for personal injury or property damage from exposure to asbestos. ( )

(e) Special Management – Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) ( )

(f) Standard Management – Cases that do not fall into any one of the other tracks. (X)

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